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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,878

09/27/2005

Kenji Yasuda

2005-0296A

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SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

08/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,878

Applicant(s)

YASUDA, KENJI

Examiner

MICHAEL HOBBS

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The preliminary amendment filed on 02/25/2005 has been entered for the record.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: on line 3 of claim 12, there is no antecedent basis for the "electrodes correspond one-to-one with each region[s]".
4. Appropriate corrective action is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 6-13 and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugihara et al. (WO 99/34202) (will be referred to as Sugihara) in view of Yasuda et al. (US 7,092,154 B1) (will be referred to as Yasuda).

The applied reference, Yasuda, has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

8. Sugihara discloses a cell potential measuring electrode used to measure the electrophysiological activities of a sample that for claim 6 includes a plural micro-electrodes mounted on an insulating substrate (page 3 lines 8-10) that are placed in plural positions enclosed by a wall (page 3 lines 14-16). Sugihara is silent regarding a semi-permeable membrane covering the wells.

9. Yasuda discloses an apparatus for microscopic observation of long-term cultures that includes the cells being formed onto a substrate covered with a semi-permeable membrane. For claim 6, Yasuda discloses that the membrane used to cover the cells is an optically transparent membrane (col. 2 lines 57-58) and the membrane is coarse enough to prevent cells from passing through the membrane (col. 2 lines 58-59). Therefore, it would be obvious to one of ordinary skill in the art to employ the membrane as suggested by Yasuda in order to retain the cells within the wells of Sugihara. The suggestion for doing so at the time would have been in order to prevent the cells from coming out of the hole or well (col. 2 lines 59-61).

10. For claim 7, as discussed above for claim 6, Sugihara has electrodes that measure the electrophysiological properties of a sample and is fully capable of stimulating nerve cells (see also MPEP § 2115). With regards to claims 8 and 15, Sugihara discloses that the micro-electrodes and reference electrodes are formed of layers of nickel plating, gold plating and platinum black on an indium-tin oxide (ITO) film (page 4 lines 20-21). While not specifying that the electrodes are made of ITO (which is

transparent), it is well within the skills of one of ordinary skill in the art to make electrodes out of ITO in order to have transparent electrodes. Furthermore, the use of ITO to make electrodes is known within the art (refer to US 5,810,725).

11. With regards to claims 9 and 16-18, Sugihara discloses a matrix of micro-electrodes that contains up to 64 micro-electrodes which reads on at least three electrodes (page 4 lines 9-11). Furthermore, the micro-electrodes are fully capable of being operated independently.

12. With regards to claims 10 and 19-25, Sugihara further discloses that the electrode sites or compartments are formed by applying the ITO film to a glass substrate and the conductive pattern is formed by photo-resist and etching (page 10 lines 15-16). The insulating film is formed by a negative photosensitive polyimide film or photo-curable resin (page 10 lines 16-17).

13. With regards to claims 11 and 12, Sugihara further discloses that the electrodes are separated by an insulating layer as discussed above and that cells are measured by the micro-electrodes and the electrodes are fully capable of measuring a cell on the electrodes (page 13 lines 29-32).

14. For claim 13, Sugihara discloses attaching the substrate containing the electrode arrays to a holder (holder 3 & 4; page 11 lines 22-23) where the electrical contacts for the microelectrodes (electrode 34) are attached to an amplifier (amplifier 24; page 13 lines 21 and 22). The cells are observed by an inverted microscope (microscope 21) that optically measures the cells and a computer is used for processing the output signal from the cells on the holder (page 6 lines 26-29). While not specifying that the

cells are nerve cells, it is within the skills of one of ordinary skill in the art to use nerve cells as the tissue sample to be stimulated by the electrodes of Sugihara (also refer to US 5,810,725).

15. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugihara et al. (WO 99/34202) (will be referred to as Sugihara) in view of Yasuda et al. (US 7,092,154 B1) (will be referred to as Yasuda) and in further view of Varalli et al. (US 2001/0041830 A1) (will be referred to as Varalli).

16. Both Sugihara and Yasuda are silent regarding the amplifier and computer being optically connected.

17. Varalli discloses an apparatus for measuring the content of glucose, lactate and other metabolites in biological fluids. Varalli also includes a measurement instrument that is connected to a patient and that transmits the data from the measuring device back to a computer. For claim 14, Varalli discloses that the connection between the measurement instrument and an external computer is an IR optical transmission system ([0037]). Other optical transmission systems that are known and used, for example, for connections between computers and peripheral units (for example, between the HP-42S and a printer) include protocols such as IRLAP (from the Infrared Data Association) and the Infrared Physical Layer Link which is used on some HP components ([0038]). Therefore, it would be obvious to one of ordinary skill in the art to employ the optical connections suggested by Varalli in order to connect the electrode array of Sugihara and Yasuda with a computer. The suggestion for doing so at the time would have been

in order to guarantee the total electrical isolation of the electrical circuits for the measurement system ([0037]).

18. Claims 6-13 and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugihara et al. (WO 99/34202) (will be referred to as Sugihara) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni).

19. Sugihara discloses a cell potential measuring electrode used to measure the electrophysiological activities of a sample that for claim 6 includes a plural micro-electrodes mounted on an insulating substrate (page 3 lines 8-10) that are placed in plural positions enclosed by a wall (page 3 lines 14-16). Sugihara is silent regarding a semi-permeable membrane covering the wells.

20. Hänni discloses a device for organic cell culture for testing the electrophysiological activity of nerve cells. For claim 6, Hänni discloses that a transparent porous membrane (membrane 16) is placed on the support structure (support 11) in order to cover an opening (opening 15; col. 3 lines 9-11). Therefore, it would be obvious to one of ordinary skill in the art to employ the membrane as suggested by Hänni in order to retain the cells within the wells of Sugihara. The suggestion for doing so at the time would have been in order to provide a cover for the opening (col. 3 lines 11-12).

21. For claim 7, as discussed above for claim 6, Sugihara has electrodes that measure the electrophysiological properties of a sample and is fully capable of stimulating nerve cells (see also MPEP § 2115). With regards to claims 8 and 15,

Sugihara discloses that the micro-electrodes and reference electrodes are formed of layers of nickel plating, gold plating and platinum black on an indium-tin oxide (ITO) film (page 4 lines 20-21). While not specifying that the electrodes are made of ITO (which is transparent), it is well within the skills of one of ordinary skill in the art to make electrodes out of ITO in order to have transparent electrodes. Furthermore, the use of ITO to make electrodes is known within the art (refer to US 5,810,725).

22. With regards to claims 9 and 16-18, Sugihara discloses a matrix of micro-electrodes that contains up to 64 micro-electrodes which reads on at least three electrodes (page 4 lines 9-11). Furthermore, the micro-electrodes are fully capable of being operated independently.

23. With regards to claims 10 and 19-25, Sugihara further discloses that the electrode sites or compartments are formed by applying the ITO film to a glass substrate and the conductive pattern is formed by photo-resist and etching (page 10 lines 15-16). The insulating film is formed by a negative photosensitive polyimide film or photo-curable resin (page 10 lines 16-17).

24. With regards to claims 11 and 12, Sugihara further discloses that the electrodes are separated by an insulating layer as discussed above and that cells are measured by the micro-electrodes and the electrodes are fully capable of measuring a cell on the electrodes (page 13 lines 29-32).

25. For claim 13, Sugihara discloses attaching the substrate containing the electrode arrays to a holder (holder 3 & 4; page 11 lines 22-23) where the electrical contacts for the microelectrodes (electrode 34) are attached to an amplifier (amplifier 24; page 13

lines 21 and 22). The cells are observed by an inverted microscope (microscope 21) that optically measures the cells and a computer is used for processing the output signal from the cells on the holder (page 6 lines 26-29). While not specifying that the cells are nerve cells, it is within the skills of one of ordinary skill in the art to use nerve cells as the tissue sample to be stimulated by the electrodes of Sugihara (also refer to US 5,810,725).

26. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugihara et al. (WO 99/34202) (will be referred to as Sugihara) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni) and in further view of Varalli et al. (US 2001/0041830 A1) (will be referred to as Varalli).

27. Both Sugihara and Hänni are silent regarding the amplifier and computer being optically connected.

28. Varalli discloses an apparatus for measuring the content of glucose, lactate and other metabolites in biological fluids. Varalli also includes a measurement instrument that is connected to a patient and that transmits the data from the measuring device back to a computer. For claim 14, Varalli discloses that the connection between the measurement instrument and an external computer is an IR optical transmission system ([0037]). Other optical transmission systems that are known and used, for example, for connections between computers and peripheral units (for example, between the HP-42S and a printer) include protocols such as IRLAP (from the Infrared Data Association) and the Infrared Physical Layer Link which is used on some HP components ([0038]).

Therefore, it would be obvious to one of ordinary skill in the art to employ the optical connections suggested by Varalli in order to connect the electrode array of Sugihara and Hänni with a computer. The suggestion for doing so at the time would have been in order to guarantee the total electrical isolation of the electrical circuits for the measurement system ([0037]).

Conclusion

29. Claims 6-25 are rejected.
30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sugihara et al. (US 5,810,725) discloses a planar electrode with electrodes formed of ITO that when combined with a microscope, observes the long term change when nerve cells are stimulated by an applied current.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M.H./